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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,853	08/13/2003	Randall V. Sparer	P-10998.00	9178

26813 7590 02/15/2011

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ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/640,853
Filing Date: August 13, 2003
Appellant(s): SPARER ET AL.

Ann Mueting
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/29/2010 appealing from the Office action mailed 07/27/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/640,714

10/640,702

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 89-150 pending.

Claims 90,105-133 and 139 withdrawn.

Claims 89,91-104,134-138 and 140-150 rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,153,252	Hossainy	11-2000
6,110,483	Whitbourne	8-2000
US 2002/0082679 A1	Sirhan	6-2002
6,576,019	Atala	6-2003

Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier

Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1).

Sirhan teaches a luminal prosthesis that can be in the form of a stent, the stent can further contain a rate-controlling element formed from polymers including cellulose acetate butyrate (CAB), polyethylene vinyl acetate (PEVA), polyurethane, polycarbonates, polymethylmethacrylate and the like and mixtures and combinations thereof, the rate controlling element provides for a controlled release of at least one active ingredient that can be contained within the element. See abstract, [0046]-[0050],[0053] and claims 1,18,74-76,80-82,112-118 and 126. The active ingredient included numerous therapeutics including dexamethasone, azatioprine and prednisone, all of the above active ingredients are also disclosed as active ingredients within applicants own specification. See claim 18 and [0030]. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than 3 $J^{1/2}cm^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitations of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer

blend that controls the delivery of the active agent, this is met by Sirhan who teaches a method to make the same polymer blend as claimed by applicant, the blend incorporated a bioactive agent, therefore the polymer blend would control the delivery of the bioactive agent in the same way as applicants claims since the same composition will inherently have the same properties.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252).

Hossainy teaches a coating for stents and a method for forming the coated stent having a film forming biocompatible polymer coating in which different polymers may be used for different layers (polyurethanes, polyamides, polyesters, polymethacrylates polyolefins, ethylene methyl methacrylate copolymers various hydrophilic celluloses and many other hydrophobic and hydrophilic polymers were specifically listed) in which the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents (including fluorouracil which is disclosed as an active ingredient within applicants own specification). See col 1 lin 6-9, col 2 lin 9-19, col 4 lin 15-col 5 lin 38, col 7 lin 5-11, lin 56-col 8 lin 35, col 9 lin 20-25, fig. 6 and 7. See col 7 lin 18-55. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than 3 $J^{1/2}cm^{3/2}$, Hossainy teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or

substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitations on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483).

Whitbourne teaches a coating for biomedical devices (including stents) and the method to make the coatings in which the coating is a blend of a stabilizing polymer and an active agent comprised of a hydrophilic polymer (the blends can include the following: polyurethanes, acrylic polymers, methacrylic polymers, vinyl acetal polymers, polyethers, PVP, epoxy polymers, several hydrophilic celluloses and numerous other stabilizing and hydrophilic polymers/copolymers) the coating also comprises a bio-active agent contained within (including thymol which is disclosed as an active ingredient within applicants own specification). See col 1 lin 5-12, lin 65-col 2 lin 24, lin 31-38, lin 43-47, col 3 lin 21-59, col 4 lin 13-36, col 5 lin 28, lin 41-46, col 7 lin 15-17, lin 55-56, col 9 lin 29-32, 50-54 and claim 17. Regarding the selection of the first and second

polymer and active ingredient based upon their solubility parameters being no greater than 3 $J^{1/2}cm^{3/2}$, Whitbourne teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Whitbourne who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims

Claims 89,91-97,99,101-103,134-138 and 140-143,145,147-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Atala (US 6,576,019).

Atala teaches biocompatible synthetic or natural polymeric matrixes for tissue reconstruction. See abstract and claims. The polymeric matrix could be formed from materials in which both polyurethane and polyphenylene oxide could be selected as a

blend. See claim 3. The polymeric matrix itself could be treated with additives or drugs prior to implantation to promote the formation of new tissue. See col 7 lin 58-col 8 lin 20. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a the range 3 $J^{1/2}cm^{3/2}$, Atala teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and active ingredients will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Claims 89,91-97,99,101-103,134-138,140-143,145,147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed, for the reasons set forth in the previous office action filed 09/11/2008.

Atala is disclosed above. The Atala patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters

increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Atala is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Atala discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Atala in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91-97,99,101-103,134-138,140-143,145,147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 6,576,019 B1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156.

The Atala patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater

the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Atala is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Atala discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Atala in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier, cited by applicants.

Sirhan is disclosed in the previous office action filed 01/29/2009. The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films

and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Sirhan discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Sirhan in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156.

The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Sirhan discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Sirhan in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier, cited by applicants.

Hossainey is disclosed in the previous office action filed 01/29/2009. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Hossainey discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers

found within Hossainey in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156.

The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Hossainey discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a

reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Hossainey in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3rd ed., Elsevier, cited by appellants.

Whitbourne is disclosed in the previous office action filed 01/29/2009. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Whitbourne discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other

one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Whitbourne in order to calculate which polymers are likely to form blends when mixed together.

Claims 89,91,93-104,134-138, 140-141 and 143-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156, cited by appellants.

The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of

Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Whitbourne discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Whitbourne in order to calculate which polymers are likely to form blends when mixed together.

(10) Response to Argument

In regards to the 35 U.S.C. 102(b) and 102(e) rejections appellants assert there is no teaching or suggestion in Sirhan, Whitbourne, Hossainey or Atala on tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited relationships of solubility parameters of the polymers and active at a predetermined amount over a period of time not controlled by porosity. Furthermore appellants contend that there the references above are silent with respect to the diffusivity of each polymer relative to a target diffusivity and swellability of the polymer blend.

The examiner notes the above argument but does not find it persuasive. The claimed method of tuning the delivery of an active agent recites the same steps of forming a polymer blend with the recited relationships of solubility parameters of the

polymers and active found in previous claim sets. Since the implants described by Hossainey, Whitbourne, Sirhan and Atala teach the same types of polymer blends and active agents it is inherent that the same composition will have the same the same properties including its ability of "tuning" the active agent, the claimed solubility parameter relationships, diffusivity, swellability and the release of the active. To meet the claimed method the examiner conducted his search based upon the active steps recited within the claims, that is a method of receiving a first and second polymer as claimed in combination with the claimed active to form an implantable device. The recited "tuning the delivery of the active" was seen as being met if all of the active steps recited in the claim body were met. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Appellants assert in regards to the 35 U.S.C. 102(b) and 102(e) rejections that the references teach several different classes of polymers, thus appellants surmise that the references each specify a vast number of individual polymer species. Appellants further contend that there is no guidance within the references above to select the same polymer blend claimed with the recited relationships of solubility parameters.

First with respect to Sirhan and Atala the polymer blend described is claimed, all US patents are considered valid thus, there is adequate guidance and direction for the claimed polymers. As mentioned in past actions both the Hossainey and Whitbourne references clearly teach the same first and second polymers claimed by appellants. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting applicants claimed second polymer and also claims an active agent that included several cellulose derivatives and polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the scope of the claims and in the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainy appellants claimed drug delivering polymer blend and the method to produce it. Furthermore while the references above teach and claim numerous polymer blends, this only supports the fact that polymer blends are a well known, old and mature field. One of ordinary skill in the art would know from the teachings of the references and what is generally well known and established in the art that numerous polymers can be blended or mixed together to form coatings for medical devices. In the same regard appellants specification and claims are also broad in the number of types of polymers that can be blended, but the examiner has concluded that appellants have provided enough written description and showed enablement since the

field of polymer blends is well known and very mature field, thus there are currently no 112 1st paragraph rejections over the breadth of the claims. However appellants argue, contradictory, that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible. A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As detailed above the examiner concluded from the prior art that polymer blends used as coatings for medical articles is a very mature field, thus the breadth of the number of possible combinations would not preclude one of ordinary skill in the art from envisioning nearly any combination of polymers that are described as being capable of being blended. Thus the examiner believes there is adequate support and guidance within each reference so that one of ordinary skill in the art would have readily envisaged applicants claimed invention from the disclosure of references cited.

Appellants assert in regards to the 35 U.S.C. 103(a) rejections, that there is no teaching or suggestion in the combination of references of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend with the recited solubility parameter relationships over a period of time not controlled by porosity. Furthermore appellants contend that there the references above are silent with respect to the diffusivity of each polymer relative to a target diffusivity and swellability of the polymer blend.

In regards to the teachings of Sirhan, Whitbourne, Hossainey and Atala, the examiner for the reasons of record above respectfully disagrees. With respect to the secondary references Van Krevlen and Coleman, clearly as noted on the record these references establish that the use of solubility parameters to predict solubility of compounds is a well known, old and established scientific principle. Appellants believe that the inventiveness of their claimed invention stems from the fact that like dissolves like, a well known and old scientific principle. As noted by Coleman and Van Krevlen one of ordinary skill could simply find the solubility parameters of the claimed polymers and active agents in a book or software program, if the solubility parameters were close, as in the claimed invention, it would be obvious that the blend is miscible. A miscible polymer blend would advantageously provide a homogeneous system for a stent coating.

Appellants assert in regards to the 35 U.S.C. 103(a) rejections that the recited references above do not provide a teaching or suggestion that would direct one of ordinary skill in the art to select appellants claimed subset of polymer and active agent combinations from the innumerable combinations described within each. Appellants purport the case law of KSR International Co. v.Teleflex Inc. (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007) and Sud-Chemie, inc v. Multisorb Technologies support their contention that while the references above describe classes of polymers that may be blended it is taken from innumerable species that have different properties including solubility

parameters and without guidance for this selection the combinations above cannot render the claims obvious.

The examiner respectfully disagrees. While the examiner notes the case law provided above the current issue differs from the specific cases cited above. In regards to guidance for Sirhan and Atala the polymer blend described is claimed, all US patents are considered valid, thus there is adequate guidance and direction for the claimed polymers since they are in fact claimed. The examiner also relies on his remarks above regarding Hossainy and Whitbourne and why it one of ordinary skill in the art could have readily envisaged or obviously selected the claimed blend. Regardless appellant's remarks seem to only point out that guidance is not provided in the primary reference when the rejections were made in combination with the secondary references Van Krevelen and Coleman. Clearly as set forth above Sirhan, Whitbourne, Hossainey and Atala are silent in regards to solubility parameters; however both Van Krevelen and Coleman describe how to calculate solubility parameters and use them to predict miscibility. Both Van Krevelen and Coleman describe that when two compounds are close in their solubility parameters the greater the likelihood that they will be miscible with each other. Therefore even though Sirhan, Whitbourne, Hossainey and Atala do not describe selecting polymers based upon their solubility parameters the guidance to select polymers by miscibility based upon solubility parameters was well known at the time of appellants claimed invention. As described in the rejections above one of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers and actives found within Sirhan, Whitbourne, Hossainey and Atala in order

to calculate which polymers and actives are likely to form miscible blends when mixed together.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W Rogers/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612